REMARKS

The Office Action mailed on March 20, 2002, has been received and reviewed. Claims 1-27 are currently pending in the above-referenced application. Each of claims 1-27 stands rejected.

The claim amendments that are presented herein have been made solely for the purpose of clarity, and not in response to any requirement of perceived requirement by the Office.

Reconsideration of the above-referenced application is respectfully requested.

Rejections Under 35 U.S.C. § 102(b)

Claims 1-27 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 6,004,295 to Langer et al. (hereinafter "Langer").

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Independent claim 1 of the above-referenced application recites a power syringe which includes a syringe barrel that includes a receptacle, a plunger insertable into the receptacle and moveable longitudinally therethrough, and a handle. The handle includes a first member and a second member. The first member of the handle is configured to be held by a first part of a user's hand and is pivotally connected to the syringe barrel. The second member is configured to be held by a second part of a user's hand and is pivotally connected to the plunger. The first and second members are connected to one another in pivotal relation.

Langer describes, among other things, a guide catheter 54 with a plunger 38 therein and an operator wire 40 secured thereto to facilitate movement of the plunger 38 through the guide catheter 54. As shown in and described with reference to FIGs. 3 and 7A of Langer, an end of the operator wire 40 is secured to a jaw of a mechanical scissors-style pivoted handle 48′. Thus, that jaw of the mechanical scissors-style pivoted handle 48′ is not connected to the plunger itself.

The other jaw of the mechanical scissors-style pivoted handle 48′ is secure to the guide catheter 54. Langer does not include any express or inherent description that the jaws of the mechanical scissors-style pivoted handle 48′ are pivotally secured to either the operator wire 40 or the guide catheter 54.

As Langer lacks any express or inherent description of a handle including a first member "pivotally connected" to a syringe barrel, of a second member "pivotally connected" to a plunger, and of a second member which is connected to a plunger, it is respectfully submitted that Langer does not anticipate each and every element of independent claim 1.

Accordingly, it is respectfully submitted that, under 35 U.S.C. § 102(b), independent claim 1 is allowable over Langer.

Claims 2-10 are each allowable, among other reasons, as depending either directly or indirectly from claim 1, which is allowable.

Claim 2 is further allowable since Langer neither expressly nor inherently describes a power syringe which includes a barrel retaining member for releasably retaining a syringe barrel.

Claim 3 is additionally allowable because Langer does not expressly or inherently describe a power syringe that includes a plunger retaining member for releasably retaining a plunger.

Claim 5 is also allowable since Langer lacks any express or inherent description of a power syringe which includes a handle with at least one of the first and second members thereof comprising a slot through which a hinge extends. Instead, the description of Langer is limited to a mechanical scissors-style pivoted handle 48′ which merely includes a simple scissors-style hinge (*see* FIGs. 3 and 7A).

Claim 6, which depends from claim 5, is further allowable since Langer includes no express or inherent description of a power syringe which includes a handle with at least one of the first and second members comprising an arcuate slot through which a hinge extends. Rather, the description of Langer is limited to a mechanical scissors-style pivoted handle 48′ which merely includes a simple scissors-style hinge (*see* FIGs. 3 and 7A).

Claim 7, which also depends from claim 5, is additionally allowable because Langer neither expressly nor inherently describes that either the first or second member of the mechanical scissors-style pivoted handle 48′ described therein includes a slot with teeth that cooperate with teeth of a hinge that pivotally connects the first and second members. Again, the description of Langer is limited to a mechanical scissors-style pivoted handle 48′ which merely includes a simple scissors-style hinge (*see* FIGs. 3 and 7A).

Claim 8 depends from claim 7 and is also allowable since Langer lacks any express or inherent description that teeth of a hinge and teeth of a slot of a handle mutually engage each other to facilitate controlled movement of the hinge along a length of the slot.

Claim 9 is further allowable since Langer does not expressly or inherently describe a power syringe with a handle member that is configured to facilitate gripping thereof. Instead, each of the members of the mechanical scissors-style pivoted handle 48′ depicted in FIGs. 3 and 7A includes a scissors-style loop, which is configured to receive a finger or thumb, not to be gripped.

Claim 10 is additionally allowable because Langer lacks any express or inherent description that a member of the described mechanical scissors-style pivoted handle 48′ may be angled. To the contrary, the mechanical scissors-style pivoted handles 48′ that are depicted in FIGs. 3 and 7A of Langer include straight handle members.

Independent claim 11 recites a handle for a power syringe. The handle includes a first member configured to be secured in pivotal relation to a syringe barrel and a second member configured to be secured in pivotal relation to a syringe plunger. The first and second members of the handle are pivotally secured to one another.

As explained previously herein, Langer does not expressly or inherently describe that either jaw of the mechanical scissor-style pivoted handle 48′ thereof may be secured in pivotally relation to either a syringe barrel or a syringe plunger. Moreover, since one jaw of the mechanical scissor-style pivoted handle 48′ described in Langer is secured to an operation wire 40 which is in turn connected to a plunger 38, Langer lacks any express or inherent description of

a handle which includes a "member [which is] configured to be secured in pivotal relation to a syringe plunger . . ."

Therefore, Langer does not anticipate each and every element of independent claim 11. Accordingly, it is respectfully submitted that, under 35 U.S.C. § 102(b), independent claim 11 is allowable over Langer.

Each of claims 12-20 is allowable, among other reasons, as depending either directly or indirectly from claim 11, which is allowable.

Claim 13 is additionally allowable since Langer lacks any express or inherent description of a syringe handle with at least one of the first and second members thereof comprising a slot through which a hinge extends. Instead, the description of Langer is limited to a mechanical scissors-style pivoted handle 48′ which merely includes a simple scissors-style hinge (*see* FIGs. 3 and 7A).

Claim 14, which depends from claim 13, is further allowable since Langer includes no express or inherent description of a syringe handle with at least one of the first and second members thereof comprising an arcuate slot through which a hinge extends. Rather, the description of Langer is limited to a mechanical scissors-style pivoted handle 48′ which merely includes a simple scissors-style hinge (*see* FIGs. 3 and 7A).

Claim 15, which also depends from claim 13, is additionally allowable because Langer neither expressly nor inherently describes that either the first or second member of the mechanical scissors-style pivoted handle 48′ described therein includes a slot with teeth that cooperate with teeth of a hinge that pivotally connects the first and second members. Again, the description of Langer is limited to a mechanical scissors-style pivoted handle 48′ which merely includes a simple scissors-style hinge (*see* FIGs. 3 and 7A).

Claim 16 depends from claim 15 and is also allowable since Langer lacks any express or inherent description that teeth of a hinge and teeth of a slot of a handle mutually engage each other to facilitate controlled movement of the hinge along a length of the slot.

Claim 17 is further allowable since Langer does not expressly or inherently describe that a member of a handle of a power syringe may include a barrel retaining member pivotally

secured thereto. Instead, the description of Langer is limited to a mechanical scissors-style pivoted handle 48′ which includes one jaw that is secured directly to a guide catheter 54.

Claim 18 depends from claim 17 and is also allowable since Langer neither expressly nor inherently describes a power syringe handle which includes a barrel retaining member configured to releasably secure a syringe barrel.

Claim 19 is additionally allowable because Langer includes no express or inherent description of a power syringe handle that includes a member with a plunger retaining member pivotally secured thereto. Rather, the description of Langer is limited to a handle for moving a plunger 38 along a conduit of a guide catheter 54, which handle includes a jaw secured to an operation wire 40 that is, in turn, secured to the plunger 38.

Claim 20, which depends from claim 19, is also allowable because Langer does not expressly or inherently describe a plunger retaining member which is is configured to releasably secure a syringe plunger.

Turning now to independent claim 21, a method for introducing a fluid into a body is recited. The method of independent claim 21 includes coupling one of an injection apparatus and an infusion apparatus to a syringe barrel in communication with a receptacle of the syringe barrel. In addition, the method of independent claim 21 includes pivoting a first handle associated with the syringe barrel and a second handle associated with a syringe plunger toward one another to force said syringe plunger into a receptacle of the syringe barrel. When such pivoting is effected, the first handle pivots relative to the syringe barrel, the second handle pivots relative to the syringe plunger, the syringe plunger displaces fluid within the receptacle to force the fluid through the injection apparatus or infusion apparatus and into the body.

It is respectfully submitted that Langer does not anticipate each and every element of independent claim 21. In particular, Langer lacks any express or inherent description that, in use, either jaw of the mechanical scissors-style pivoted handle 48′ of the assembly described therein with reference to FIGs. 3 and 7A pivots relative to a syringe barrel (*i.e.*, the guide catheter 54) or a syringe plunger (*i.e.*, plunger 38).

It is, therefore, respectfully submitted that, under 35 U.S.C. § 102(b), independent claim 21 is allowable over Langer.

Claims 22-27 are each allowable, among other reasons, as depending either directly or indirectly from claim 21, which is allowable.

Claim 22 is additionally allowable because the description of Langer is limited to methods for delivering fluids (*see, e.g.*, col. 1, lines 64-67), and, thus, for creating positive pressure within a guide catheter 54. Contrary to the assertion that has been made in the outstanding Office Action that col. 1, lines 22 and 23, and col. 5, lines 40-56 of Langer describe methods for creating negative pressure within a guide catheter, it is respectfully submitted that Langer lacks any express or inherent description of methods for creating a negative pressure within the sampling fluids, as col. 1, lines 22 and 23 describes use of catheters for angioplasty, while col. 5, lines 40-56 describe use of the catheter to insert a needle 36 into a body organ wall.

As such, Langer does not expressly or inherently describe a method for sampling fluids or otherwise drawing fluid into the guide catheter 54 described therein, as recited in claim 23.

Claim 27 is additionally allowable since Langer neither expressly nor inherently describes introducing an indicator solution into a body.

In view of the foregoing, it is respectfully requested that the 35 U.S.C. § 102(b) rejections of claims 1-27 be withdrawn.

CONCLUSION

It is respectfully submitted that each of claims 1-27 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing the allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,

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Date: June 20, 2002

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APPENDIX B

(VERSION OF SUBSTITUTE SPECIFICATION EXCLUDING CLAIMS WITH MARKINGS TO SHOW CHANGES MADE)

(Serial No. 09/864,967)

PATENT
Attorney Docket 4623US

CERTIFICATION UNDER 37 C.F.R. § 1.10
NOTICE OF EXPRESS MAILING

Express Mail Mailing Label Number: EL740535759US

Date of Deposit with USPS: May 24, 2001

Person making Deposit: Jared Turner

APPLICATION FOR LETTERS PATENT

for

HAND-HELD, HAND-OPERATED POWER SYRINGE AND METHODS

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TITLE OF THE INVENTION

HAND-HELD, HAND-OPERATED POWER SYRINGE AND METHODS

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention relates generally to apparatus for facilitating the movement of a plunger of a syringe through a barrel of the syringe and, more particularly, to hand-held, hand operated apparatus that facilitate the movement of a plunger through a syringe barrel. More specifically, the present invention relates to hand-held apparatus with scissor grip type leveraged triggering systems that force a plunger of a syringe through the length of the barrel of the syringe.

Background of Related Art

[0002] Apparatus that facilitate the ejection of fluids from syringes are well known. Such apparatus are often referred to as fluid delivery devices or power syringes.

[0003] Conventionally, fluid delivery devices have been used to inject liquids, such as contrasting media (*e.g.*, dyes, carbon dioxide, etc.) and medicines into patients. With many fluid delivery devices, the rate at which a fluid is injected into a patient's body may be controlled. While some of these devices are automated, others may be manually operated.

[0004] Due to the increase in delivery force provided by fluid delivery devices, such devices are particularly useful for injecting high viscosity fluids, which would otherwise be difficult, if not impossible, to inject by forcing one's thumb against the plunger of a conventional hand-held syringe.

[0005] Some hand-held power syringes, such as that disclosed in U.S. Patent 5,330,074, issued to Wirsig et al. (hereinafter "the '074 Patent"), include ratcheting type mechanisms to assist a user in applying force to a plunger of the syringe. Ratcheting mechanisms are, however, often complex and, consequently, add to the manufacturing costs of such hand-held power syringes.

[0006] Other hand-held fluid delivery devices include handles with a fixed member and a moveable member associated therewith. In one example of such a syringe, disclosed in U.S. Patent 6,059,759, issued to Lampropoulos et al. (hereinafter "the '759 Patent"), the moveable member may be slidingly secured to the fixed member. A plunger is forced into a syringe barrel as a user squeezes the handle members toward one another. Nonetheless, such a syringe only assists the user in forcing the plunger into the syringe barrel by transferring the location where force must be applied and increasing the area of a member to which force must be applied. Alternatively, the ends of the moveable member and the fixed member of the handle may be pivotally secured to one another, as described in U.S. Patent 6,024,728, issued to Schulz (hereinafter "the '728 Patent"). In either event, an upper end of the moveable member either directly or indirectly engages a plunger of the syringe. Upon squeezing the two members of the handle, the moveable member moves toward the fixed member and forces the plunger into the barrel of the syringe. Thus, the handle of such a syringe allows the force provided by a hand squeeze to be applied to the plunger of the syringe rather than the lesser amount of force that would otherwise be provided by use of a thumb to force the plunger into the syringe. Nonetheless, these fluid delivery devices may be difficult to use when the injection of high viscosity fluids is required, which may cause physical or mental discomfort to a patient into whom the fluid is being injected.

[0007] Some fluid delivery devices ~~to~~ provide leverage to assist a user in forcing a plunger into or out of a syringe barrel. Examples of such devices are provided in U.S. Patent 6,030,368, issued to Anwar et al. (hereinafter "the '368 Patent") and 4,737,151, issued to Clement et al. (hereinafter "the '151 Patent). The devices of the '368 and '151 Patents each include three pivot points to provide the desired amount of leverage: a first pivot point connecting a handle member to a plunger; a second pivot point connecting the handle member to a base member; and a third pivot point connecting the base member to a syringe barrel. While the base members of these devices are configured to be supported upon a table top or other flat surface, the generally straight handle members of these devices are configured to receive a downward force by a user, which is transferred to the plunger. As a user need only grip and move the handle member of such a device to move the plunger, the user can apply more force to

the handle than that provided by a squeeze of the hand. Nonetheless, due to the manner in which the increased amount of force is applied, it is difficult for a user to make fine adjustments when injecting fluid into a body or extracting fluid therefrom.

[0008] Accordingly, there is a need for a fluid delivery apparatus that converts a small amount of controllable force, such as that provided by a squeeze of a hand, to a syringe plunger to faciliate movement of the plunger through a syringe barrel.

SUMMARY OF THE INVENTION

[0009] A fluid delivery apparatus incorporating teachings of the present invention is a hand-held type power syringe which includes a handle that is leveraged in such a manner as to apply an increased amount of pressure to the plunger of the syringe. The fluid delivery apparatus of the present invention may also include a syringe barrel with a fluid receptacle formed therethrough, as well as a plunger that inserts into a large end of the receptacle and that may be moved through at least a portion of the length of the receptacle.

[0010] The handle of the fluid delivery apparatus resembles a scissors and includes two members, a first of which is configured to be held by the fingers of an individual and the second of which is configured to be held by the individual's thumb or positioned against the palm of the individual. One or both of the first and second handle members may be bent so as to enable a user to grip both members with one hand; while maximizing the amount of leverage provided as the handle members are forced toward one another.

[0011] A first pivot point of the handle pivotally connects the two members to one another at substantially central locations along the lengths thereof. When the first and second members of the handle are moved toward or away from one another, the first pivot point may remain in a substantially fixed position along the lengths of both the first and second members. Alternatively, the first pivot point may move in an elongate path relative to one or both of the first and second members of the handle as the positions of the first and second members are changed relative to one another. By way of example only, the first pivot point may move either eccentrically or in a linear fashion relative to one of the handle members as the positions of the members change; while remaining substantially stationary relative to the other handle member.

[0012] A second pivot point of the handle may be associated with the syringe barrel such that the second pivot point itself remains relatively stationary to the syringe barrel as the fluid delivery device is being used. The second member of the handle is either directly or indirectly connected to the syringe barrel at the second pivot point.

[0013] The first member of the handle is connected, either directly or indirectly, to the plunger of the syringe at a third pivot point. Upon movement of the plunger into or out of the receptacle of the syringe barrel, the third pivot point remains substantially stationary relative to the plunger.

[0014] In both reusable and single-use embodiments of the fluid delivery apparatus of the present invention, the second member of the handle may be connected directly to an integral syringe barrel at the second pivot point, while the first member of the handle may be connected directly to an integral plunger at the first pivot point.

[0015] An alternative embodiment of the fluid delivery apparatus of the present invention is configured to receive a conventional, disposable syringe. In such an embodiment, the second member of the handle may be connected at the second pivot point to a syringe barrel retaining element which, in turn, receives the barrel of the disposable syringe. The first member of the handle may be connected at the third pivot point to a plunger-retaining element which, in turn, engages a portion of the plunger of the disposable syringe.

[0016] As an example of the use of a fluid delivery apparatus incorporating teachings of the present invention, a fluid to be injected into a patient may be drawn into the receptacle of the syringe barrel by moving the first and second members away from one another. Air may then be removed from a catheter or needle (*e.g.*, a hypodermic needle or biopsy needle) that communicates with an end of the receptacle by squeezing the first and second members of the handle toward one another and the consequent movement of the plunger partially into the receptacle of the syringe barrel. If a catheter is coupled to the syringe, the catheter may be introduced into the patient or coupled with a catheter that has already been introduced into the patient. The fluid may then be injected into the patient through the needle or one or more catheters by further squeezing of the first and second handle members, which results in the

plunger being moved further into the receptacle of the syringe barrel and displacement of fluid located in the receptacle and the catheter.

[0017] Other features and advantages of the present invention will become apparent to those of ordinary skill in the art through consideration of the ensuing description, the accompanying drawings, and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] In the drawings, which illustrate exemplary embodiments of fluid delivery apparatus incorporating teachings of the present invention and features thereof:

[0019] FIG. 1 is a side view of a power syringe incorporating teachings of the present invention, including a syringe barrel, a plunger that is longitudinally moveable within a receptacle of the syringe barrel, and a scissor-grip handle that includes two members with three pivotal connection points, a first between a first member of the handle and the syringe barrel, a second between the second member of the handle and the plunger, and a third between the two handle members;

[0020] FIGs. 1A-1C are cross-sections taken along lines 1A–1A, 1B–1B, and 1C–1C, respectively, of FIG. 1;

[0021] FIG. 2 is a cross-sectional representation of the syringe barrel of the power syringe of FIG. 1, illustrating the syringe barrel in an assembled relationship with a catheter;

[0022] FIG. 3 is a cross-sectional representation of a variation of the syringe barrel illustrated in FIGs. 1 and 2, which includes an aspiration port that may communicate with a source or reservoir for introducing fluid into the syringe barrel upon appropriate movement of the plunger to increase the available volume within the syringe barrel;

[0023] FIG. 4 is a side view that depicts a variation of the handle of FIG. 1, with one of the first and second members including an arcuate slot through which a movable connection member on the other of the two members moves when the handle members are moved relative to one another;

[0024] FIG. 5 is a side view that depicts another variation of the handle of FIG. 1, wherein one of the first and second handle members includes a partial gear member and the other

of the first and second handle members includes an elongated slot with teeth along an edge thereof for receiving teeth of the partial gear member upon movement of the two handle members relative to one another;

[0025] FIG. 6 is a side view of an alternative embodiment of a power syringe incorporating teachings of the present invention, wherein a disposable syringe barrel and plunger may be assembled and used with a reusable injection/aspiration handle; and

[0026] FIGs. 7-7B are schematic representations of use of a power catheter incorporating teachings of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0027] FIG. 1 illustrates an exemplary embodiment of a fluid delivery apparatus, or power syringe 10, incorporating teachings of the present invention. Power syringe 10 includes a barrel 20, a plunger 30 associated with barrel 20, and a scissor-grip handle 40 which causes plunger 30 to move longitudinally relative to barrel 20. One or both of barrel 20 and plunger 30 may be removable from handle 40 to facilitate the replacement of these elements and the reuse of handle 40.

[0028] Barrel 20 of power syringe 10 is an elongate member with a hollow interior extending through the length thereof. Along the majority of its length, barrel 20 is substantially uniform in both cross-sectional shape and cross-sectional dimensions. The region of barrel 20 having such substantial cross-sectional uniformity is referred to herein as body 22. As depicted, body 22 extends from a proximal end 21p of barrel 20 to a tapered section or region 24 thereof. A syringe tip 25 is located on the opposite side of tapered section 24, at the distal end 21d of barrel 20.

[0029] As shown in FIGs 1-1C, the distances across opposed points of various cross-sections taken transverse to longitudinal axis A_B of barrel 20 on the outer surface of barrel 20 or the outer diameter of barrel 20 are collectively referred to herein as OD20. The corresponding distances across opposed points of various cross-sections taken transverse to longitudinal axis A_B on the inner surface of barrel 20 or the inner diameter of barrel 20 are collectively referred to herein as ID20.

[0030] As is depicted in FIGs. 1 and 1A, both OD20A and ID20A remain substantially the same along the substantial length of a body 22 of barrel 20. At tapered region 24, OD20 and ID20, which are respectively depicted at one location along the length of tapered region 24 as OD20B and ID20B, gradually (either linearly or along a curve) decrease from the sizes of OD20A and ID20A of body 22 to the much smaller sizes OD20C and ID20C of syringe tip 25. At syringe tip 25, the sizes of OD20C and ID20C are again substantially constant.

[0031] It is preferred that the taper of tapered region 24 occur at an angle of about 15° to longitudinal axis A_B of barrel 20. Other taper angles are, however, also within the scope of the present invention.

[0032] Turning now to FIG. 2, within body 22 and tapered region 24 of barrel 20, the hollow interior thereof forms a receptacle 23. The volume of receptacle 23 is preferably suitable for the desired use of power syringe 10 (FIG. 1). For example, in applications where only small volumes of materials will be injected or aspirated with power syringe 10, barrel 20 may include a receptacle 23 with a relative small volume (*e.g.*, 5 cubic centimeters ("cc"), 10 cc, etc.). When power syringe 10 is to be used to inject or aspirate larger volumes of materials, the volume of receptacle 23 may also be larger (*e.g.*, 20cc, 30cc, 60cc, etc.). Alternatively, receptacle 23 of barrel 20 may have other standard syringe volumes or a volume that is tailored to a specific use for power syringe 10.

[0033] The hollow interior of syringe tip 25 is referred to herein as a lumen 26. Lumen 26 may have a diameter of as small as about 1mm (0.40 inch) or smaller. Of course, syringe tips 25 with different sizes of lumens 26 are within the scope of the present invention, as the size of a lumen 26 depends at least partially upon the gauge of a needle or the lumen size of a catheter to be coupled with syringe tip 25.

[0034] In addition, in order to facilitate the coupling of a needle or catheter with syringe tip 25, syringe tip 25 includes a coupling member 27 at or near the distal end 21d of barrel 20. Although FIG. 1 depicts coupling member 27 as including a ~~cylindrically-shaped~~cylindrically shaped recess that extends partially into syringe tip 25, coupling members of other configurations, including, without limitation, threaded or nonthreaded coupling members that

facilitate the coupling of a needle, catheter, or other member to an outer surface of syringe tip 25, are also within the scope of the present invention.

[0035] As illustrated in FIG. 3, a variation of barrel 20′ may include an aspiration port 80 proximate syringe tip 25. Aspiration port 80 facilitates the introduction of a fluid, such as a saline solution, medicine, anesthetic, indicator solution (*e.g.*, dye, radioactive solution, radioopaque solution or x-ray contrast media, etc.), other chemical compound, or the like from an external source into receptacle 23 of barrel 20. Aspiration port 80 is depicted as comprising a cylindrical protrusion 81, which is configured to have a length of tubing coupled thereto, and a lumen 82 that extends through protrusion 81 and communicates with lumen 26 of syringe tip 25. In addition, aspiration port 80 may include a valve 83, such as a stop cock type valve, which opens and closes lumen 82. Of course, other configurations of aspiration ports are also within the scope of the present invention.

[0036] Referring again to FIG. 1, barrel 20 also includes a handle connection element 28. As depicted, handle connection element 28 extends from body 22 at proximal end 21p of barrel 20 and includes an aperture formed therethrough. The aperture is sized and configured to receive a hinge element 70 and, thus, to facilitate the connection of a member of handle 40 to barrel 20.

[0037] While FIG. 1 depicts barrel 20, receptacle 23, and lumen 26 as having substantially cylindrical shapes with circular cross-sections taken transverse to a longitudinal axis A_B of barrel 20, syringe barrels with any other suitable cross-sectional shapes (*e.g.*, ovals, ellipses, polygons, etc.) are also within the scope of the present invention.

[0038] With continued reference to FIG. 1, plunger 30 is an elongate member with dimensions that permit plunger 30 to be inserted into receptacle 23 of barrel 20 through proximal end 21p thereof. Plunger 30 includes a body 32 and a head 34 at the distal end 31d of body 32. The proximal end 31p of body 32 and, thus, of plunger 30 is configured to have force applied thereto to facilitate movement of plunger 30 in both directions along a longitudinal axis A_P of plunger 30.

[0039] Head 34 of plunger 30 preferably comprises a somewhat deformable, resilient member. By way of example, head 34 may be formed from silicone or any other resilient

polymer (*i.e.*, rubber) that is suitable for use in medical applications. The shape of head 34 is preferably substantially complementary to a shape of the portion of receptacle 23 of barrel 20 that is located within tapered region 24 and a portion of body 22 adjacent thereto. The size of head 34 is preferably substantially the same as or somewhat larger than the correspondingly shaped portion of receptacle 23 so as to facilitate the substantial displacement of fluid from receptacle 23 as plunger 30 is fully inserted therein.

[0040] Preferably, in order to facilitate movement of head 34 of plunger 30 along the full length of receptacle 23, the length of plunger 30 is greater than the combined lengths of body 22 and tapered region 24 of barrel 20. Of course, in order to apply the amount of force necessary to move plunger 30 through the length of receptacle 23, body 32 of plunger 30 is preferably formed from a more rigid material than that of head 34. Accordingly, head 34 preferably includes a receptacle (not shown) that is configured to receive a corresponding head connection protrusion (not shown) at the distal end of body 32, as known in the art.

[0041] Proximal end 31p of plunger 30 includes a handle connection element 38. Handle connection element 38 includes an aperture formed through body 32 of plunger 30 at a location that facilitates the pivotal connection of a member of handle 40 thereto by way of a hinge element 70.

[0042] In addition, proximal end 31p of plunger 30 may include a secondary movement element 36, such as a loop or another member by which an individual may cause plunger 30 to move in one or both directions along longitudinal axis A_p thereof.

[0043] Still referring to FIG. 1, handle 40 includes two elongate members, a first member 50 and a second member 60. First member 50 and second member 60 are pivotally connected with one another in a manner that, along with the shapes of first and second members 50 and 60, provides leverage so as to decrease the amount of force that must be exerted by an individual's hand to move plunger 30 relative to barrel 20.

[0044] First member 50, which is configured to be held with an individual's fingers, includes a gripping end 52 and a plunger attachment end 58. In addition, first member 50 includes pivotal connection element 56 positioned at a central region 55 thereof, which is located substantially centrally along the length thereof, to facilitate connection of first member 50 to

second member 60 of handle 40. Pivotal connection element 56 includes an aperture that has a circular shape and that receives a hinge element 70, or pivot pin, which, in turn, connects first member 50 and second member 60 to one another.

[0045] As shown, first member 50 includes an elongated loop 53 along gripping end 52, through which an individual's fingers may be inserted. Alternatively, or in addition to loop 53, gripping end 52 may include a finger grip 54 that is contoured so as to comfortably receive the fingers of an individual.

[0046] Plunger attachment end 58 includes a plunger connection element 59 that facilitates the pivotal connection of first member 50 to the corresponding handle connection element 38 of plunger 30. Plunger connection element 59 may comprise an aperture that is configured to receive hinge element 70. First member 50 and plunger 30 are pivotally connected to one another by positioning plunger attachment end 58 against the appropriate location of plunger 30 with plunger connection element 59 and ~~the~~ aperture 39 of handle connection element 38 in alignment. A single hinge element 70 is then inserted through both plunger connection element 589 and aperture 39 of handle connection element 38. Hinge element 70 preferably includes an enlarged head 71 at each end thereof to maintain the assembled, pivotal relationship of plunger 30 and first member 50. Of course, other known types of pivotal connection arrangements between plunger 30 and first member 50 and their corresponding elements are also within the scope of the present invention.

[0047] First member 50 is bent, or angled, at some point along the length thereof, between gripping end 52 and plunger attachment end 58, to at least partially provide the desired amount of leverage for forcing plunger 30 to move longitudinally through receptacle 23 of barrel 20. As shown in FIG. 1, first member 50 is angled at two locations, a first of which is located between gripping end 52 and central region 55 and a second of which is located between central region 55 and plunger attachment end 58. Although FIG. 1 depicts gripping end 52 and central region 55 as being oriented at an angle of about 140° relative to one another and central region 55 and plunger attachment end 58 as being oriented at an angle of about 90° relative to one another, other angles and bend locations are also within the scope of the present invention.

[0048] Still referring to FIG. 1, second member 60 of handle 40 is an elongate member that is configured to be held by an individual's palm or thumb. Second member 60 includes a gripping end 62 and a barrel attachment end 68, as well as a central region 65 located between gripping end 62 and barrel attachment end 68.

[0049] Gripping end 62 of first member 60 may include a thumb loop 63 through which the thumb of an individual using power syringe 10 may be inserted.

[0050] Central region 65 of second member 60 includes a pivotal connection element 66 that corresponds to pivotal connection element 56 of first member 50. Pivotal connection element 66 may comprise an aperture formed through central region 65 and configured to receive hinge element 70. Upon properly orienting first member 50 and second member 60 relative to one another in an assembled relationship thereof and aligning the aperture of first member 50 with the aperture of second member 60, hinge element 70 may be inserted through the apertures to pivotally connect first and second members 50 and 60 to one another. Hinge element 70 preferably includes an enlarged head 71 at each end thereof to maintain the assembled, pivotal relationship of first member 50 and second member 60.

[0051] Alternatively, as depicted in FIG. 4, a variation of pivotal connection element 66′ may comprise an arcuate slot 67′, along the length of which pivotal connection element 56 may move as first and second members 50 and 60 are moved toward or apart from one another.

[0052] As another alternative, shown in FIG. 5, a handle 40″ of a power syringe according to the present invention includes another embodiment of connection ~~member~~element 56″ on central region 55″ of first member 50″ and another, corresponding embodiment of pivotal connection element 66″ on central region 65″ of second member 60″. Connection ~~member~~element 56″, which protrudes from central region 55″ and is fixed in relation thereto, includes a cylindrical section 56a″, a series of adjacent teeth 56b″ protruding from at least a portion of the curved surface of cylindrical section 56a″, and an enlarged retention head 56c″ adjacent cylindrical section 56a″, opposite from the remainder of first member 50″. The distance that cylindrical section 56a″ protrudes from central region 55″ of first member 50″ is preferably slightly larger than the thickness of second member 60″.

[0053] The corresponding pivotal connection element 66″ of second member 60″ comprises an elongated slot 66a″ with a series of adjacent teeth 66b″ protruding from at least a portion of an edge along the length of slot 66a″. Teeth 66b″ are configured and positioned complementarily to teeth 56b″ of connection ~~member~~element 56″ such that teeth 56b″ and teeth 66b″ cooperate by mutually engaging each other upon rotation of cylindrical section 56a″ relative to slot 66a″. The width of slot 66a″ is preferably slightly larger than the diameter of cylindrical section 56a″ of pivotal connection element 56″ so as to substantially prevent side-to-side movement of pivotal connection element 56″ relative to pivotal connection element 66″. Consequently, the relative movement of pivotal connection elements 56″ and 66″ with respect to one another ~~are~~is substantially confined on the direction in which pivotal connection element 66″ extends, which, as illustrated, is along the length of second handle 60″. Thus, when first and second handle members 50″ and 60″ are forced toward one another, pivotal connection element 56″ rotates relative to pivotal connection element 66″ and moves downward through slot 66a″ of pivotal connection element 66″. Conversely, when first and second handle members 50″ and 60″ are forced apart from one another, pivotal connection element 56″ rotates and moves in the opposite direction relative to pivotal connection element 66″.

[0054] Referring again to FIG. 1, when first and second members 50 and 60, or variations thereof, have been properly assembled with one another, it is preferred that practically any adult user be able to properly position their fingers on gripping end 52 and their thumb or palm against gripping end 62 while gripping ends 52 and 62 are spaced a maximum distance apart from one another with head 3~~2~~4 of plunger located at proximal end 21p of barrel 20.

[0055] Barrel attachment end 68 includes a barrel connection element 69 that facilitates the pivotal connection of second member 60 to the corresponding handle connection element 28 of barrel 20. As depicted, barrel connection element 69 comprises an aperture that is configured to receive a hinge element 70. Second member 60 and barrel 20 are pivotally connected to one another by properly positioning barrel ~~connection~~attachment end 68 and handle connection element 28 against one another, with the apertures thereof in alignment, and inserting ~~of~~ a single hinge element 70 through both barrel connection element 6~~8~~9 and handle connection element 28. Hinge element 70 preferably includes an enlarged head 71 at each end thereof to maintain the

assembled, pivotal relationship of barrel 20 and second member 60. Of course, other known types of pivotal connection arrangements between barrel 20 and second member 60 and their corresponding elements are also within the scope of the present invention.

[0056] Second member 60 of handle 40 may be bent, or angled, to increase the leverage provided by first member 50 and the scissor-like arrangement of first member 50 and second member 60. As illustrated, second member 60 is bent at central region 65 thereof to position gripping end 62 in proximity to gripping end 52 of first member 50 when first member 50 and second member 60 are in an appropriate assembled relationship.

[0057] Of course, one or both of first member 50 and second member 60 may include reinforcement ribs 72 or other reinforcement structures along at least a portion of the length thereof. As depicted, reinforcement ribs 72 are positioned along the edges of first member 50 and second member 60. Reinforcement ribs 72 may be positioned to prevent side-to-side bending of first member 50 or second member 60 during use of handle 40 to move plunger 30 relative to barrel 20.

[0058] Turning to FIG. 6, another embodiment of a power syringe 110 according to the present invention is illustrated. Power syringe 110 includes a scissor-grip handle 40, a barrel retaining member 120 pivotally secured to a second member 60 of handle 40, and a plunger biasing member 130 pivotally secured to a first member 50 of handle 40.

[0059] Barrel retaining member 120 is configured to engage and retain at least a portion of the barrel 220 of a syringe 200. The depicted, exemplary embodiment of barrel retaining member 120 includes a flexible, elongate member 121 with a receptacle 124 at one end 122 thereof. Receptacle 124 is configured to receive the other end 123 of elongate member 121, as well as to facilitate the movement of a received portion of elongate member 121 therethrough. When receiving end 123 of elongate member 121 has been inserted into or through receptacle 124, barrel retaining member 120 takes on an annular configuration, forming a barrel receptacle 125 that may receive a portion of barrel 220 of syringe 200. As elongate member 121 moves through receptacle 124, the size of barrel receptacle 125 changes. The position of a portion of elongate member 121 extending through receptacle 124 may be maintained by way of a size adjustment member 126 (*e.g.*, a screw, a spring-biased pin, etc.) that protrudes into

receptacle 124 to engage the portion of elongate member 121 therein. Elongate member 121 may also include retention recesses 127 (*e.g.*, grooves, slots, etc.) that are oriented along the length of elongate member 121 and that are configured to receive an interior end of size adjustment member 126 so as to further maintain the position of elongate member 121 relative to receptacle 124 and, thus, the size of barrel receptacle 125.

[0060] Barrel retaining member 120 also includes a handle connection element 128 which extends from elongate member 121 and includes an aperture 129 therethrough. Aperture 129 is sized and configured to receive a hinge element 70 and, thus, to facilitate connection of a member of handle 40 to barrel retaining member 120.

[0061] Of course, other embodiments of barrel retaining members, which may be configured to receive a variety of different sizes of syringes or single syringe sizes, are also within the scope of the present invention.

[0062] With continued reference to FIG. 6, an exemplary embodiment of plunger biasing member 130 is configured to receive, retain, and apply force to a proximal end 231p of a plunger 230 of syringe 200. Accordingly, the illustrated plunger biasing retaining member 130 includes a plunger receiving portion 131 that is configured to receive and apply pressure to proximal end 231p of plunger 230. As illustrated, plunger receiving portion 131 includes a receptacle 132 that is configured to receive at least a portion of the disk-shaped proximal end 231p of a conventionally configured syringe plunger 230. In addition, plunger biasing retaining member 130 includes a slot 134 that is continuous with ~~slot~~receptacle 132 and that is positioned and sized to receive a portion of at least one of the support ribs 234 of a conventionally configured syringe plunger 230. As depicted, proximal end 231p is substantially completely received within receptacle 132. Accordingly, slot 134 may include a narrow bottom section that receives a single, vertically oriented support rib 234 and a wider top section that receives opposed, horizontally oriented support ribs 234.

[0063] A handle connection element 138 is positioned adjacent to (beneath) plunger receiving portion 131 and includes an aperture 139 that is configured to receive a portion of a hinge element 70 and to pivotally connect plunger biasing member 130 to first member 50 of handle 40.

[0064] Handle 40 of power syringe 110 may be configured as described previously herein.

[0065] While the various elements of power syringe 10 may be manufactured from any suitable material or materials, it is preferred that each of the elements of power syringe 10 be formed by injection molding processes so as to afford low manufacturing cost and, consequently, to permit the disposal of at least barrel 20 and plunger 30 of power syringe 10 after use. For the more rigid elements of power syringe 10, which include substantially all of the elements thereof with the exception of head 34 of plunger 30, polycarbonates, such as ~~Lexan®~~LEXAN®, manufactured by General Electric, or ~~Makrolon®~~MAKROLON®, manufactured by Miles Chemicals, may be used. Of course, other medical grade plastics having properties (strength, rigidity, structural integrity, ability to be adequately sterilized while maintaining other desired properties, etc.) that are suitable for the desired functions of the various elements of power syringe 10 may be used to form those elements. Alternatively, suitable metals, such as stainless steel, which have the desired properties may be used to form one or more of the elements of power syringe 10. However, these configurations are not requirements and the materials and method of fabrication are not critical to the invention.

[0066] Turning now to FIGs. 7-7B, an example of the use of a power catheter incorporating teachings of the present invention is illustrated.

[0067] FIG. 7 illustrates the introduction of a fluid 300 into receptacle 23 of barrel 20 through either lumen 26 of syringe tip 25 (FIGs. 1 and 2) or lumen 82 of aspiration port 80 (FIG. 3) by drawing plunger 30 outwardly (proximally) through receptacle 23. Plunger 30 may be drawn outwardly through receptacle 23 by a user~~'s~~ U forcing first and second members 50 and 60 of handle 40 apart from one another. As plunger 30 is drawn outwardly through receptacle 23, the available volume of receptacle 23 (*i.e.*, that located distally relative to head 34 of plunger 30) increases and a negative pressure is created within receptacle 23. This negative pressure forces fluid 300 to enter receptacle 23. As depicted, fluid 300 is a liquid, such as a medicine, an anesthetic, a dye, or another chemical compound. Alternatively, fluid 300 may comprise a gas, air, or another mixture of gases.

[0068] As shown in FIG. 7A, syringe tip 25 may be coupled to a known infusion or injection apparatus 302, shown in phantom, such as a catheter or a hypodermic needle. Infusion or injection apparatus 302 comprises a conduit which facilitates the introduction of fluid 300 into the body of an individual.

[0069] In FIG. 7B, as user U forces first member 50 and second member 60 toward one another, plunger 30 is forced inwardly (*i.e.*, distally) through receptacle 23, decreasing the available volume within receptacle 23 and creating an increase in pressure therein. This increase in pressure within receptacle 23 forces fluid 300 out of receptacle 23 through lumen 26 of syringe tip 25, through infusion or injection apparatus 302, and into the body of the individual. With valve 83 in a closed position or orientation, fluid 300 is prevented from escaping through lumen 82 of aspiration port 80 as the pressure within receptacle 23 is being increased. The amount of fluid introduced into the individual's body may be controlled by controlling the distance first and second members 50 and 60 are forced together.

[0070] Returning reference to FIG. 1, the three-pivot-point configuration of handle 40 provides sufficient leverage that the force applied by a single hand of a user will be translated into an adequate amount of force upon plunger 30 and within receptacle 23 to force even relatively high viscosity fluids into and out of receptacle 23. Moreover, the configurations of members 50 and 60 of handle 40 facilitate gripping thereof with a single hand, the fine motor skills of which can be used in such a way as to precisely control the amount of fluid being introduced into or discharged from receptacle 23 of syringe barrel 20.

[0071] Power catheters incorporating teachings of the present invention may be used in a variety of different procedures, including, without limitation, injecting medicines or drugs into an individual~~'~~, either through a hypodermic needle into ~~individual I's~~the individual's tissues or intravenously (*i.e.*, into a vein of an individual~~'~~), introducing dyes or other indicator solutions into the bloodstream of a particular location of ~~individual I's~~individual's body (*e.g.*, in angiography), introducing a gas, air, or another gas mixture into an angioplasty balloon to inflate the same in a process which is typically referred to as percutaneous transluminal coronary angioplasty ("PTCA"), or obtaining samples of blood, other fluids, or tissues (*e.g.*, with a biopsy needle or other biopsy instrument). A power syringe according to the present invention may also

be used to remove air or gas from such a balloon or to obtain samples from the body of an individual~~.~~, as well as in other applications where syringes have been used.

[0072] Although the foregoing description contains many specifics, these should not be construed as limiting the scope of the present invention, but merely as providing illustrations of some exemplary embodiments. Similarly, other embodiments of the invention may be devised which do not depart from the spirit or scope of the present invention. Features from different embodiments may be employed in combination. The scope of the invention is, therefore, indicated and limited only by the appended claims and their legal equivalents, rather than by the foregoing description. All additions, deletions, and modifications to the invention, as disclosed herein, which fall within the meaning and scope of the claims are to be embraced thereby.

ABSTRACT

A hand-held power syringe. The power syringe includes a handle with pivotally connected first and second members. The first member is also pivotally connectable to a syringe barrel, while the second member is pivotally connectable to a syringe plunger. These three pivotal connections provide leverage for forcing high viscosity fluids into and out of a receptacle of the syringe barrel. One or both of the first and second members of the handle may be bent to facilitate a user's gripping and movement of the first and second handle members. The power syringe may be used in any suitable injection, infusion, or sample-obtaining application, including angiography and angioplasty.

APPENDIX D

(VERSION OF CLAIMS AS AMENDED HEREIN WITH MARKINGS TO SHOW CHANGES MADE)

(Serial No. 09/864,967)

VERSION OF CLAIMS WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please amend the claims as follows:

1. (Amended) A power syringe, comprising:

a syringe barrel including a receptacle for receiving fluid;

a plunger insertable into said receptacle and moveable longitudinally therethrough; and

a handle, including:

a first member configured to be held by a first part of a user's hand, said first member being pivotally connected to said syringe barrel; and

a second member configured to be held by a second part of [a] the user's hand, said second member being pivotally connected to said plunger, said first and second members being connected to one another in pivotal relation.

2. (Amended) The power syringe of claim 1, [further comprising] wherein said first member is pivotally connected to said syringe barrel by way of a barrel retaining member for releasably retaining said syringe barrel.

3. (Amended) The power syringe of claim 1, [further comprising] wherein said second member is pivotally connected to said plunger by way of a plunger retaining member for releasably retaining said plunger.

9. (Amended) The power syringe of claim 1, wherein at least one of said first and second [handles] members is configured to facilitate gripping thereof.

10. (Amended) The power syringe of claim 9, wherein said at least one of said first and second [handles] members is angled.

11. (Amended) A handle for a power syringe, comprising:
a first member configured to be secured in pivotal relation to a syringe barrel; and
a second member configured to be secured in pivotal relation to a syringe plunger, said first and second members being pivotally secured to one another.

12. (Amended) The handle of claim 11, further comprising a hinge that extends through apertures formed through said first and second members to secure said first and second members in said pivotal relation.

14. (Amended) The handle of claim 13, wherein said slot [includes] comprises an arcuate slot.

20. (Amended) The handle of claim 19, wherein said [barrel] plunger retaining member is configured to releasably secure the syringe plunger.

21. (Amended) A method for introducing a fluid into a body, comprising:
coupling one of an injection apparatus and an infusion apparatus to a syringe barrel in communication with a receptacle of said syringe barrel; and
pivoting a first handle associated with said syringe barrel and a second handle associated with a syringe plunger toward one another to force said syringe plunger into [a] said receptacle of said syringe barrel, said first handle pivoting relative to said syringe barrel, said second handle pivoting relative to said syringe plunger, said syringe plunger displacing fluid within said receptacle to force the fluid through said injection apparatus [of] or said infusion apparatus and into the body.